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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/403,269	10/18/1999	ULF LINDAHL	003300-589	7046

26111 7590 07/10/2003

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1100 NEW YORK AVENUE, N.W.
WASHINGTON, DC 20005

EXAMINER

STEADMAN, DAVID J

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 07/10/2003

28

Please find below and/or attached an Office communication concerning this application or proceeding.

FILE COPY

Office Action Summary

Application No.

09/403,269

Applicant(s)

LINDAHL ET AL.

Examiner

David J. Steadman

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21,25,33-35,38-43,47,55-57,60-65,67,68,72-85 and 103-114 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 103-106 and 108-113 is/are allowed.
- 6) ☒ Claim(s) 21,33-35,38-43,55-57,60-65,67,68,72-85,107 and 114 is/are rejected.
- 7) ☒ Claim(s) 25 and 47 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 27.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: sequence alignment.

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DETAILED ACTION

Application Status

[1] A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 26, 2003 has been entered.

[2] Claims 21, 25, 33-35, 38-43, 47, 55-57, 60-65, 67, 68, 72-85, 103-114 are pending in the application.

[3] Applicant's cancellation of claims 8, 19, 20, 22-24, 26-32, 36, 37, 44-46, 48-54, 58, 59, 66, 69-71, and 86-102 and amendment to claims 21, 43, 65, 79, and 80 in Paper No. 24, filed November 04, 2002, is acknowledged.

[4] Receipt of Information Disclosure Statements filed as Paper Nos. 27 and 29 is acknowledged.

[5] It is noted that applicant's amendment directs entry of new claims 114 and 115 in Paper No. 24. However, as no claim 113 has entered in the instant application, new claims 114 and 115 have been re-numbered according to 37 CFR 1.126 as claims 113 and 114.

Claim Rejection(s) - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

[6] Claims 80 and 107 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. It is noted that the indicated allowability of claim 107 in Paper No. 21 is withdrawn. The claims are drawn to a polynucleotide. The claim reads on a product of nature and should be amended to indicate the hand of the inventor, e.g., by insertion of "isolated". See MPEP § 2105.

Claim Rejection(s) - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

[7] Claims 65, 67, 68, 72-78, and 80-85 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 65 (claims dependent therefrom) recites the term "[a]n isolated polynucleotide... ..which hybridizes... ..to said isolated polynucleotide". The claims are rejected because claims 65 (claims 76-78 and 81-85 dependent therefrom), 67, 68, 72-75, and 80 can be interpreted as a polynucleotide that hybridizes to itself. However, based on the specification and the claims, this does not appear to be applicant's intent. As such, it is suggested that applicant clarify the meaning of the claims.

Claim Rejection(s) - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

[8] Claims 65, 68, 72, 73, 75-85, and 115 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. Claims 65 (claims 76-78 and 81-85 dependent therefrom), 68, 72, 73, 75, 79, 80, and 115 recite ranges of nucleotides as follows: 73 to 3085 of SEQ ID NO:12, 145 to 1404 of SEQ ID NO:12, and 145 to 3085 of SEQ ID NO:12. The examiner can find no support in the specification, claims, or drawings as originally filed for these nucleotide ranges. It is

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noted that claims reciting these ranges of nucleotides were added in Paper No. 16 without showing support for these limitations as required by MPEP § 714.02 and § 2163.06.

[9] Upon reconsideration, the indicated allowability of claim 107 in Paper No. 21 is withdrawn. Claim 107 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 107 is drawn to a polynucleotide encoding an amino acid sequence with a deletion of the N-terminal, C-terminal or internal regions of the polynucleotide of claim 103 and wherein the amino acid sequence has glucuronyl C5-epimerase activity. The genus of claimed polynucleotides encompasses species that have not been disclosed in the specification such as allelic variants and deletion mutants. The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. A representative number of species means that the species that are adequately described are representative of the entire genus. The specification fails to teach the structure of a single representative species of the genus of claimed polynucleotides encoding deleted amino acid sequences. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

[10] As stated above, upon reconsideration, the indicated allowability of claim 107 in Paper No. 21 is withdrawn. Claim 107 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO:12, does not reasonably provide enablement for all polynucleotides encoding an amino acid sequence with a deletion of the N-terminal, C-terminal or internal regions of the

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polynucleotide of claim 103 and wherein the amino acid sequence has glucuronyl C5-epimerase activity.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Undue experimentation would be required for a skilled artisan to make and/or use the claimed invention. Factors to be considered in determining whether undue experimentation is required, are summarized in *In re Wands* (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s). The Factors most relevant to the instant rejection are addressed below.

- The claims are overly broad in scope: Claim 107 is so broad as to encompass all polynucleotides encoding an amino acid sequence with a deletion of the N-terminal, C-terminal or internal regions of the polynucleotide of claim 103 and wherein the amino acid sequence has glucuronyl C5-epimerase activity. The scope of the claim is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polynucleotides encoding amino acid sequences having glucuronyl C5-epimerase activity broadly encompassed by the claim. In this case, the disclosure is limited to SEQ ID NO:12.

- The lack of guidance and working examples: The specification fails to provide a single working example of a deletion of SEQ ID NO:12 that maintains glucuronyl C5-epimerase activity. It is noted that, while nucleotides 73 to 1404 of SEQ ID NO:12 are disclosed in the specification, there is no indication that a polypeptide encoded by these nucleotides has glucuronyl C5-epimerase activity. The specification fails to provide guidance instructing the artisan which of the amino acids of SEQ ID NO:13 is necessary for glucuronyl C5-epimerase activity and which N- or C-terminal or internal residues of SEQ ID NO:13 can be deleted with an expectation that such encoding nucleic acid would encode a polypeptide having glucuronyl C5-epimerase activity.

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- The high degree of unpredictability of the art: The ability to predict those amino acids which are necessary for catalytic activity of a given protein and which amino acids can be deleted with an expectation of having glucuronyl C5-epimerase activity would *not* be considered routine experimentation, particularly in view of the lack of guidance and working examples provided by the specification.
- The amount of experimentation: In view of the broad scope of the claim, the lack of guidance and working examples, and the high degree of unpredictability as stated above, a skilled artisan would recognize the amount of experimentation required to make all polynucleotides encoding an amino acid sequence with a deletion of the N-terminal, C-terminal or internal regions of the polynucleotide of claim 103 and wherein the amino acid sequence has glucuronyl C5-epimerase activity is clearly undue.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988).

Claim Rejection(s) - Double Patenting

[11] Claims 21, 33-35, 38-43, 55-57, and 60-64 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 7-9, and 11 of copending Application No. 10/005,647. Although the conflicting claims are not identical, they are not patentably distinct from each other because the polypeptide encoded by the polynucleotide of claims 1-5, 7-9, and 11 of copending Application No. 10/005,647 are not limited to having glucuronyl C5-epimerase activity capable of converting D-glucuronic acid to L-iduronic acid. It is noted that SEQ ID NO:1 (represented by Figure 3) of copending Application No. 10/005,647 encodes a polypeptide that is 97.1% identical to amino acids 25-444 of SEQ ID NO:13 of the instant application (see attached sequence comparison).

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.


Conclusion

[12] Status of claims:

- Claims 21, 25, 33-35, 38-43, 47, 55-57, 60-65, 67, 68, 72-85, 103-114 are pending.
- Claims 21, 33-35, 38-43, 55-57, 60-65, 67, 68, 72-85, 107, and 114 are rejected but would be allowable if rewritten to overcome the rejection(s) set forth in this Office action.
- Claims 25 and 47 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
- Claims 103-106 and 108-113 are in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Thursday from 6:30 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX number for official papers filed to Group 1600 is (703) 308-4242. Draft or informal FAX communications should be directed to (703) 746-5078. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman, Ph.D.
Patent Examiner
Art Unit 1652


PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

RESULT 2

US-10-005-647-1

; Sequence 1, Application US/10005647
; Patent No. US20020127696A1
; GENERAL INFORMATION:
; APPLICANT: Jalkanen, Markku
; APPLICANT: Darwish, Kamel El
; APPLICANT: Lindahl, Ulf
; APPLICANT: Li, Jin-Ping
; TITLE OF INVENTION: Glucuronyl C5-Epimerase, DNA Encoding the Same and Uses Thereof
; FILE REFERENCE: 1708.0280002
; CURRENT APPLICATION NUMBER: US/10/005,647
; CURRENT FILING DATE: 2001-12-07
; PRIOR APPLICATION NUMBER: US 60/304,180
; PRIOR FILING DATE: 2000-12-08
; PRIOR APPLICATION NUMBER: US 09/732,026
; PRIOR FILING DATE: 2000-12-08
; NUMBER OF SEQ ID NOS: 2
; SOFTWARE: PatentIn version 3.0
; SEQ ID NO 1
; LENGTH: 1854
; TYPE: DNA
; ORGANISM: Mus musculus
; FEATURE:
; NAME/KEY: CDS
; LOCATION: (1)..(1854)
US-10-005-647-1

Alignment Scores:

Pred. No.:	4.64e-266	Length:	1854
Score:	2145.00	Matches:	406
Percent Similarity:	98.81%	Conservative:	9
Best Local Similarity:	96.67%	Mismatches:	5
Query Match:	97.10%	Indels:	0
DB:	12	Gaps:	0

US-09-403-269-13_COPY_25_444 (1-420) x US-10-005-647-1 (1-1854)

Qy	1	LeuSerThrGlnTrpGlyProGlnGlyTyrPheTyrProIleGlnIleAlaGlnTyrGly	20
Db	595	TTATCTACCCAGTGGGGCCTCAAGGCTATTTCTACCCAATCCAGATTGCACAGTATGGG	654
Qy	21	LeuSerHisTyrSerLysAsnLeuThrGluLysProProHisIleGluValTyrGluThr	40
Db	655	CTAAGTCATTACAGCAAGAATCTAACCAGAGAAACCCCTCACATAGAAGTATATGAAACA	714
Qy	41	AlaGluAspArgAspLysAsnSerLysProAsnAspTrpThrValProLysGlyCysPhe	60
Db	715	GCAGAAGACAGGGACAGAAACATCAGACCTAATGAATGGACTGTGCCCAAGGGGTGCTTC	774
Qy	61	MetAlaSerValAlaAspLysSerArgPheThrAsnValLysGlnPheIleAlaProGlu	80
Db	775	ATGGCCAGTGTGGCAGACAAGTCTAGATCCCAATGTTAAACAGTTTATTGCTCCAGAA	834
Qy	81	ThrSerGluGlyValSerLeuGlnLeuGlyAsnThrLysAspPheIleIleSerPheAsp	100
Db	835	ACCAGTGAAGGTGTGTCTTTGAGCTGGGAAACACAAAAGACTTCATTATTTTATTGAC	894
Qy	101	LeuLysPheLeuThrAsnGlySerValSerValValLeuGluThrThrGluLysAsnGln	120
Db	895	CTCAAGCTTTTAAACAAATGGGAGTGTGTCTGTGGTTCTGGAGACCACAGAAAAGATCAG	954
Qy	121	LeuPheThrValHisTyrValSerAsnThrGlnLeuIleAlaPheLysGluArgAspIle	140
Db	955	CTCTTCACTGTGCATTATGTCTCAAACACCCAGCTGATTGCTTTCAGAGACAGGGACATA	1014
Qy	141	TyrTyrGlyIleGlyProArgThrSerTrpSerThrValThrArgAspLeuValThrAsp	160
Db	1015	TACTACGGCATTGGGCCAGAACTTCATGGAGTACAGTTACCAGAGACCTGGTCACTGAC	1074
Qy	161	LeuArgLysGlyValGlyLeuSerAsnThrLysAlaValLysProThrArgIleMetPro	180

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Db 1075 |||||CTCAGGAAAGGAGTGGGCCCTTTCTAACACAAAAGCTGTCAAGCCAACCAAAATCATGCCC 1134
Qy 181 LysLysValValArgLeuIleAlaLysGlyLysGlyPheLeuAspAsnIleThrIleSer 200
Db 1135 |||||AAAAAGGTGGTTAGGTTGATTGCAAAAGGGAAGGGATTCTTGACAACATTACCATCTCA 1194
Qy 201 ThrThrAlaHisMetAlaAlaPhePheAlaAlaSerAspTrpLeuValArgAsnGlnAsp 220
Db 1195 |||||ACCACAGCCCACATGGCTGCATTCTTTGCTGCAAGTGACTGGCTAGTGAGGAACCAGGAT 1254
Qy 221 GluLysGlyGlyTrpProIleMetValThrArgLysLeuGlyGluGlyPheLysSerLeu 240
Db 1255 |||||GAGAAAGGTGGCTGGCCAATTATGGTGACCGGAAGTTAGGGGAAGGGTTAAATCTTTA 1314
Qy 241 GluProGlyTrpTyrSerAlaMetAlaGlnGlyGlnAlaIleSerThrLeuValArgAla 260
Db 1315 |||||GAACCAGGATGGTACTCTGCCATGGCACAAGGGCAAGCCATCTCTACCTAGTCAGGGCC 1374
Qy 261 TyrLeuLeuThrLysAspHisIlePheLeuAsnSerAlaLeuArgAlaThrAlaProTyr 280
Db 1375 |||||TATCTTCTAACGAAAGACTATGTATTCCTCAGTTCAGCTTTAAGGGCAACAGCCCCATAC 1434
Qy 281 LysPheLeuSerGluGlnHisGlyValLysAlaValPheMetAsnLysHisAspTrpTyr 300
Db 1435 |||||AAGTTTCCGTCAGAGCAGCATGGAGTTAAAGCCGTGTTTCATGAATAAACATGACTGGTAT 1494
Qy 301 GluGluTyrProThrThrProSerSerPheValLeuAsnGlyPheMetTyrSerLeuIle 320
Db 1495 |||||GAAGAATATCCAACCACACCTAGCTCTTTTGTGTTTAAATGGCTTTATGTATTCTTTAATT 1554
Qy 321 GlyLeuTyrAspLeuLysGluThrAlaGlyGluLysLeuGlyLysGluAlaArgSerLeu 340
Db 1555 |||||GGGCTGTATGACCTAAAAGAAACAGCAGGGGAGACACTTGGGAAAGAAGCAAGGTCCTTG 1614
Qy 341 TyrGluArgGlyMetGluSerLeuLysAlaMetLeuProLeuTyrAspThrGlySerGly 360
Db 1615 |||||TACGAGCGCGGCATGGAATCTCTTAAAGCCATGCTGCCCTTGTATGATACTGGCTCCGGG 1674
Qy 361 ThrIleTyrAspLeuArgHisPheMetLeuGlyIleAlaProAsnLeuAlaArgTrpAsp 380
Db 1675 |||||ACCATCTATGACCTCCGCCACTTCATGCTTGGCATTGCTCCCAACCTGGCCCGCTGGGAC 1734
Qy 381 TyrHisThrThrHisIleAsnGlnLeuGlnLeuLeuSerThrIleAspGluSerProIle 400
Db 1735 |||||TATCACACCACCCACATTAACCAGCTGCAGCTGCTCAGCACCATCGATGAGTCCCAATC 1794
Qy 401 PheLysGluPheValLysArgTrpLysSerTyrLeuLysGlySerArgAlaLysHisAsn 420
Db 1795 |||||TTCAAAGAATTTGTCAAGAGGTGAAAAGCTACCTTAAAGGCAGTAGGGCAAAGCACAAAC 1854

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